TESTIMONY ON BEHALF OF ALLIANCE IMAGING, INC. AND ALLIANCE ONCOLOGY, LLC REGARDING STANDARDS FOR TRANSFER OF OWNERSHIP AND SITE FOR PRACTICES ESTABLISHED PURSUANT TO SO-CALLED PHYSICIAN EXEMPTIONS

This testimony is submitted on behalf of Alliance Imaging, Inc. and Alliance Oncology, LLC, which I refer to as Alliance. Alliance is a leading provider of diagnostic medical imaging and a provider of radiation therapy services with over twenty years experience delivering services in the Commonwealth. It operates licensed clinics and manages clinics and physician practices. Many of the services it provides are located on the campuses of or in joint ventures with community hospitals.

In this testimony, I refer to innovative services and new technology as "**New Technology Practices**" regardless of the legal authority under which they were established.

The Department has asked for recommendations on interpreting and implementing Section 100.246(D), which provides in pertinent part that no person who has acquired a New Technology Practice pursuant to a so-called physician exemption "may implement an addition, expansion, conversion, transfer of site or transfer of ownership of such equipment unless the Department is first notified pursuant to 105 CMR 100.246(D) and ***determines there is need therefore***…" (emphasis supplied). The Department has informally indicated that it may interpret the words "***determines there is need therefore***" to mean a full determination of need review is required under the standards of Section 100.553.

Alliance's recommendations are guided by the principle articulated by the Department in promulgating the regulations that have engendered this hearing: that the rules applied by the Department to New Technology Practices should be the same regardless of whether a New Technology Practice is established pursuant to a so-called physician exemption letter or a determination of need ("DoN"). Alliance agrees with the Department's attempt to create a level playing field with regard to the provision of innovative services and new technology.

Based on that principle, Alliance can see no reason why the standards for approving the transfer of ownership or site of a New Technology Practice should vary depending upon the nature of the entity owning the Practice, its corporate structure or its licensure status.

First, treating all providers the same is a basic requirement of creating a level playing field. Second, as a matter of fact, there is usually no difference operationally on the ground between a New Technology Practice established pursuant to a so-called physician exemption letter or a DoN, regardless of how organized or licensed. In most cases, neither a patient served nor the staff providing the service will have any idea of how the practice was established, or its ownership, corporate structure or licensure status.

The way New Technology Practices are owned and their licensure status is often a matter of historical accident or convenience that has no bearing on their current operation. When filing notices of intent to acquire PET, MRI or radiation therapy equipment, some physician groups filed multiple letters in the name of a single legal entity; others filed multiple letters, each in the

name of a different legal entity even though each such entity was commonly owned. One group of physicians might own five New Technology Practices in five separate legal entities in multiple locations; another group of physicians might own five New Technology Practices in one legal entity. There is no reason that these practices should be subject to different standards when their owners seek to sell them or transfer their location.

Since the time they were originally established, New Technology Practices have changed hands in various ways and have assumed numerous forms and licensure status. Some New Technology Practices, originally established by solo physicians or groups of physicians, are now owned by large physician-controlled corporations employing hundreds of physicians. Sometimes these corporations maintain the New Technology Practice as a separate legal entity; sometimes the New Technology Practice is incorporated as one service of the ownership entity. It is also worth noting the fact that while eligible to license all their New Technology Practices as clinics, these entities have opted to license some as clinics while operating others as exempt physician practices. Other New Technology Practices, while owned by physician groups and operated as licensure-exempt physician practices, are enmeshed in complex joint ventures with or managed by community hospitals. While eligible to be licensed as clinics, for various reasons, some joint ventures have chosen not to do so. We are aware of at least one New Technology Practice, which, while in fact owned and controlled by a hospital, was nominally held in the name of the hospital's chief of radiology.

We cannot describe all of the legal forms under which New Technology Practices are currently organized because of the complexity of such arrangements and our lack of first hand knowledge.

The choice of organization by various practices is not based on any consistent principle or rationale. Consider the example of a PET practice owned by multispecialty group: it may have been established and currently exist in a variety of legal forms. In one case, radiologists may have originally established the PET practice before joining the multispecialty group, and upon joining, formally merged the PET practice into the legal entity owning the multispecialty group; in another case, radiologists may have decided, upon joining the multispecialty group, to transfer the ownership of the **entity** owning the PET practice to the physicians owning the multispecialty group, keeping the two legal entities separate; in a third case, the multispecialty group itself may have established a PET practice as a separate legal entity; in a fourth case, the multispecialty group may have organized the PET practice as part of the legal entity owning the multispecialty group. In each case, the PET practice might be located within the four walls of the multispecialty group or in an entirely separate building. Importantly, a patient being treated would have no concept of these different legal arrangements; it is likely as well that most of the physicians in the group would have little understanding of these legal arrangements. Under any of these legal arrangements, the physical space, technicians, physicians, and office and billing matters would likely be exactly the same. There would be little or no change if the multispecialty group chose to license the practice as a clinic.

The details of a proposed sale or transfer of ownership of a New Technology Practice is much the same regardless of its legal structure or licensure status. In practice, transfers are proposed for a variety of reasons: the current owners are retiring or a physician group is breaking apart; a hospital or large physician group is seeking to purchase a New Technology Practice to

complement its existing services; a physician group believes that a professional imaging company can market and operate the New Technology Practice more efficiently and profitably. In the vast majority of cases, the transfer of the New Technology Practice will involve a purchase and sale of only the assets utilized in the New Technology Practice whether that practice is freestanding – meaning the sole practice owned by the selling entity - or part of a medical practice involving other services, such as in the case of a multispecialty group or clinic.

Assets transferred in a sale always will include the regulatory authority (to the extent transferable), good will, along with as many other assets in a particular case as is practical or otherwise required. Sometimes it includes contracts (for staff and otherwise), equipment and supplies, leases or real estate, and receivables. The major equipment such as magnetic resonance imaging or PET may be included in the sale, depending on, among other issues, its age, condition and state of its technology. It is very important to point out that in a transfer of a New Technology Practice, it is not the equipment that is transferred but rather the practice. Equipment rarely is sold in isolation. Normally equipment is one asset of a larger group of assets making up the sale of a practice.

We can see no reason why the Department would subject a proposed sale of a New Technology Practice to different standards based on whether it is the only service owned by the selling entity or whether it is part of an entity providing multiple services. Similarly, we see no distinction between selling merely the assets of a New Technology Practice, which is the usual case, or selling the legal entity that owns the New Technology Practice. We can also see no reason to treat the sale differently depending on the licensure status. When New Technology Practices are functionally the same regardless of how they are owned or licensed, they should be treated the same for purposes of Department review prior to the sale. Of course, if the acquiring owner of a New Technology Practice is subject to licensure, then the requirements of the particular licensure statute must be met.

These conclusions are based not only on the inequity of treating virtually indistinguishable New Technology Practices differently, but also because distinguishing transfers of ownership of a New Technology Practice merely on the basis of either ownership structure or licensure status would not serve a rational policy goal. For instance, it would mean that a physician group that owned six PET practices in a single legal entity, each on the grounds of a different hospital, and which treated each New Technology Practice as a separate economic operation, would be subject to one set of standards while a New Technology Practice that was the sole practice owned by a legal entity, would be subject to a different standard, even if that New Technology Practice was one of several New Technology Practices under common ownership, each held in a separate legal entity, no matter how much it and the other commonly owned New Technology Practices were enmeshed in operations. Similarly, it would mean that an entity owning a single freestanding MRI clinic might be able to sell its New Technology Practice while a physician group owning a single freestanding unlicensed New Technology Practice might not. It would mean that the determination of whether a multispecialty practice would be able to transfer its PET practice would depend on the historical and often idiosyncratic basis of how it was organized or whether it was licensed. The consequences of review based on such distinctions are

obvious. New Technology Practices that look and operate exactly alike on the ground would be subject to different treatment.

If the general principle is that all New Technology Practices should be subject to the same rules regarding transfer of ownership, then the specific issue is what those standards should be. If the Department's goal is to create a level playing field with respect to New Technology Practices, no matter the source of regulatory authority, proposed transfers of practices established pursuant to physician letters should be treated like proposed transfers of New Technology Practices obtained pursuant to DoNs: no substantive review should be required.

Indeed, the Department's regulations do not, and the Department has never, subjected to ***any*** Department review ***whatsoever*** transfers of ownership of New Technology Practices acquired pursuant to a DoN. 105 CMR 100.110 through 100.016 do not contain any basis for Department jurisdiction to review transfers of ownership of New Technology Practices acquired pursuant to DoNs; nor is a transfer of ownership of such New Technology Practices included in the definition of "Substantial Change in Services" found in 105 CMR 100.021. Only requests for transfers of ownership of approved but unimplemented projects for New Technology Practices authorized pursuant to a DoN have been subject to Department review and approval, under 100.710. Therefore, if a single purpose clinic providing MRI services proposed to sell its MRI practice to another clinic, it would not be subject to review under the Department's regulations. We know of no case where the Department has required review. We understand that the Department takes the position that a New Technology Practice licensed as part of a clinic which provides multiple services may not be transferred apart from the transfer of the entire clinic but we see no legal or policy reason for such a position. For instance there is an office that provides MRI services at Mass General West in Waltham apparently under the auspices of Massachusetts General Hospital. It is not clear whether that office is owned by a physician practice, a licensed clinic, or Massachusetts General Hospital as a satellite operation. In any case, should the owner decide to offer it for sale, there is no reason to subject a proposed transfer to full DoN review under the standards of Section 100.533.

The most obvious reason not to impose full DoN review is that numerous New Technology Practices would not be transferable at all. First, since under the Department's guidelines, there is no need for additional MRI or, taking pending applications into account, radiation therapy capacity, and little need for more PET capacity, a request for transfer is unlikely to meet the standards of Factor 2, Health Care Requirements. Moreover, an applicant might be unable to demonstrate that the proposed project will not duplicate existing resources in the applicable service area as required by Factor 1, Health Planning Process since there is already existing capacity and competition for all of these services. In many cases, the consequence would not only be that the New Technology Practice could not be transferred to a new owner but also that it would simply go out of business. A substantial investment and important community resource would disappear. An example would be an MRI practice owned by a radiologist. What would happen to the practice if she died or retired? Since there is no need for new MRI capacity in the Commonwealth, the transfer of ownership would be denied. The MRI Practice would go out of business and the community resource would be lost.

Furthermore, subjecting the transfer of New Technology Practices to full DoN review is not good health planning policy. Practices established by physician letters or DoNs are already, by statute, legitimately a part of the existing health care resources of the Commonwealth regardless of how they are owned or regulated. Each New Technology Practice provides services to patients and is woven into the local fabric of available medical services. Under full DoN review, these services would disappear merely because a transfer of ownership was desirable or required for private reasons, and not because of reasons of allocation of that particular medical service in a given area. The Department has no legitimate interest in subjecting transfer of such practices to full DoN review and essentially shutting down these services in a random manner over time. The Department has no legitimate interest in subjecting to review for need New Technology Practices that have already been established as part of health services resources of the Commonwealth.

What should the Department do then? The Department may have a legitimate interest in assuring that a prospective transferee of an New Technology Practices (i) has the financial resources adequate to provide the associated service, (ii) has the capacity to provide a substantially consistent adequate level of care, and (iii) is suitable in terms of character and experience. Generally speaking the market will address the first concern: an undercapitalized business will not survive. The second and third objectives are assured by existing licensing reviews. If the transferee must be licensed by the Department in order to operate the New Technology Practice, the Department will review capacity to render adequate care and the character and experience of the prospective transferee in the licensure process. If the transferee is exempt from licensure as a physician practice, the Board of Registration in Medicine will perform the same function.

If the Department concludes, however, that it must apply some substantive review to transfers of ownership of New Technology Practices, then it should limit its review to the three criteria described above and should apply that review whether Mass General Hospital wants to sell its satellite MRI clinic to a group of physicians or whether a group of physicians want to sell its unlicensed MRI practice to Mass General. Not surprisingly, those criteria are exactly the criteria used by the Department in reviewing transfers of ownership of unimplemented DoNs under 105 CMR 100.710. We suggest that, if the Department decides to subject transfers of ownership to any review, it apply the criteria of 105 CMR 100.710(E)(1), (3) and (4) ***but without employing the cumbersome process otherwise contained in 105 CMR 100.710.*** There is no need to allow competitors to use the process to interfere with and slow down the legitimate interests of owners of New Technology Practices in transferring their businesses to competent providers. The Department regularly reviews providers based on the criteria set out above in its licensure process without either public participation or comment. The Department does not need input from parties who are not truly disinterested.

We strongly urge that the Department either amend 100.246(D) so that only a notice is required for transfer of ownership of New Technology Practices authorized by physician exemption letters - consistent with the still effective 1993 statute - or that, at the least, it implement that subsection to apply the criteria but not the process applicable to transfers of unimplemented DoNs, as was originally proposed by the Department. We urge the Department to apply the

same process and the same standards in the proposed sale of a New Technology Practice licensed as a clinic, or part of a clinic or a hospital satellite.

The Department has also sought testimony about the appropriate standards it should use in reviewing requests for transfers of site of New Technology Practices. With regard to those practices conducted by clinics the Department currently applies the Transfer of Site Procedures of Section 100.720(I). We believe that applying the standards in that regulation to New Technology Practices is not reasonable regardless of whether a practice is established pursuant to DoN or a physician letter, and regardless of whether it is operated by a regulated entity or a physician group. In the highly competitive diagnostic imaging and radiation therapy markets, there tends to be a number of providers in the same market. Section 100.720(I)(1) was established to compare hospital service areas not diagnostic procedures or radiation therapy treatments. It makes no sense to compare the discharge list of another facility that provides the same services in the same community as the provider attempting to change location. For instance, if 30 percent of patients of one MRI provider located in Waltham come from Waltham and 25 percent of another MRI provider also come from Waltham, should the second provider not be able to move across town in Waltham? What if the second provider loses its lease and needs to move? Certainly the competitor will utilize the terms of Section 100.720(I) to object to the proposed relocation in an attempt to destroy its competition. What will the Department do in such case? What will the Department do if a hospital-controlled joint venture is seeking to move its diagnostic practice? What will the Department do if a MRI practice owned by a multispecialty group which generates nearly all of its scans from its own patients seeks to move to another part of town, even if doing so moves the practice closer to competitors? Is the Department willing to deny these requests even if it means effectively shutting down the New Technology Practices?

Moreover, the Department has interpreted Section 100.720(I)(2) as requiring an applicant to establish need for the service at the new location. As we have demonstrated in our discussion of transfer of ownership above, that is an almost impossible burden to meet when the Department's guidelines provide for no need for these modalities. It makes no sense to subject transfers of site of New Technology Practices to standards that are impossible to meet, especially since the Department may well bend those same standards if it decides to approve a transfer of site of, say, a hospital-owned New Technology Practice.

A better idea is recognize the justifiably competitive nature of these services and allow a New Technology Practice to transfer its site except in very narrow circumstances such as moving within a few hundred yards of a competitor.

The Department should not establish or attempt to apply standards that tend to favor one class of providers or standards that are ultimately unworkable or unfair. The goal is to create a level playing field.